

wherein the suppository is adapted to be inserted into the anorectal or urogenital orifice of a human or animal so as to allow the suppository to be in contact with tissue of the anorectal or urogenital orifice to facilitate transfer of suppository material therethrough.

(Amended) 2. A suppository based vaccine delivery system for prophylaxis against urogenital tract infections in humans, said suppository comprising:

A2 (a) a vaccine or vaccine adjuvant(s) of whole or fractionated viral or other microbial pathogens, or their purified cellular constituents, whether native, mutated, synthetic, cloned or recombinantly-expressed and combinations thereof, that consists of nucleic acids, proteins, lipids, other antigenic determinants or combinations thereof capable of producing humoral or cellular-mediated immunity in humans; and

Sub B1 (b) a suppository base, selected from the group consisting of polyethylene glycol, polysorbate and combinations thereof;

wherein the suppository is adapted to be inserted vaginally so as to allow the suppository to be in contact with vaginal mucous membrane to facilitate transfer of suppository material therethrough.

Sub B1  
A2  
(Amended) 3. A suppository based vaccine delivery system for prophylaxis against anorectally transmitted infectious disease in humans or animals, said suppository comprising:

(a) a vaccine or vaccine adjuvant(s) comprising whole or fractionated viral or other microbial pathogens, or their purified cellular constituents, whether native, mutated, synthetic, cloned or recombinantly expressed and combinations thereof, that consists of nucleic acids, proteins, lipids, other antigenic determinants or combinations thereof capable of producing humoral or cellular-mediated immunity in humans or animals; and

(b) suppository base, selected from the group consisting of polyethylene glycol, polysorbate and combinations thereof;

wherein the suppository is adapted to be inserted rectally so as to allow the suppository to be in contact with the anorectal mucous membrane to facilitate transfer of vaccine or vaccine adjuvant material therethrough.

(Amended) 4. The suppository based vaccine delivery system of claim 1 wherein the vaccine content or vaccine adjuvant(s) is whole cells, purified constituents or is generated from known genetic information of urogenital or anorectally transmittable pathogens.

Sub B1  
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(Amended) 12. A suppository-based vaccine delivery system for prophylaxis against urogenital or anorectally transmitted infections in humans or animals, said suppository comprising:

(a) a vaccine or vaccine adjuvant(s) comprising purified, mutated, synthetic or genetically engineered constituents of known pathogens of urogenital pathogens, anorectally pathogens and combinations thereof; and

(b) a suppository base, selected from the group consisting of polyethylene glycol, polysorbate and combinations thereof;

wherein the polyethylene glycol suppository base is comprised of about 75% to about 98% by weight polyethylene glycol and about 2% to about 25% by weight polysorbate, wherein the polyethylene glycol has an average molecular weight of about 950 to about 3700, and wherein the polyethylene glycol suppository base comprises from about 70% to about 99% by weight of the suppository; wherein the suppository is adapted to be inserted vaginally or rectally so as to allow the suppository to be in contact with mucous membrane to facilitate transfer of vaccine or vaccine adjuvant(s) material therethrough.

(Amended) 13. A suppository-based vaccine delivery system for prophylaxis against genitourinary or anorectal tract infections in humans or animals, said suppository resulting from the mixture of:

(a) a vaccine or vaccine adjuvant comprising whole or fractionated viral or other microbial pathogens, or their purified cellular constituents, whether native, mutated, synthetic, cloned or recombinantly expressed, that consists of nucleic acids, proteins, lipids, other antigenic determinants or combinations thereof capable of producing humoral or cellular-mediated immunity in humans or animals; and

(b) a suppository base, selected from the group consisting of polyethylene glycol, polysorbate and combinations thereof;

wherein the polyethylene glycol suppository base is comprised of about 75% to about 98% by weight polyethylene glycol and about 2% to about 25% by weight polysorbate, wherein the polyethylene glycol has an average molecular weight of about 750 to about 3700,

Supp B  
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conc

and wherein the polyethylene glycol suppository base comprises from about 70% to greater than 99% by weight of the suppository base; wherein the suppository is adapted to be inserted vaginally or rectally so as to allow the suppository to be in contact with mucous membrane to facilitate transfer of vaccine or vaccine adjuvant(s) material therethrough.

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Please cancel claims 14-16.

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(Amended) 17. A method for producing an immune response in humans or animals, said method comprising the steps of:

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(a) inserting a suppository into an anorectal or urogenital orifice of a human or animal, wherein said suppository comprises a vaccine or vaccine adjuvant(s) material comprised of whole, fractionated viral or other microbial pathogens, or their purified cellular constituents, whether native, mutated, synthetic, cloned or recombinantly expressed, that consists of nucleic acids, proteins, other antigenic determinants or combinations thereof capable of producing humoral or cellular-mediated immunity against urogenital or anorectal disease in humans or animals and a suppository base, wherein the suppository base is selected from the group consisting of polyethylene glycol, polysorbate and combination thereof; and

(b) contacting the suppository with mucosal tissue at and internal to the anorectal or urogenital orifice to facilitate transfer of the vaccine or vaccine adjuvant material therethrough and induce an immune response in the human or animal.

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(Amended) 18. The method of claim 17 wherein the suppository base is comprised of about 75% to about 98% by weight polyethylene glycol and about 2% to about 25% by weight polysorbate.

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